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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,655	01/02/2002	Matthew James Sweet	8191-PA01	2089
27111	7590	03/09/2004	EXAMINER	
BROWN, MARTIN, HALLER & MCCLAIN LLP			ZARA, JANE J	
1660 UNION STREET			ART UNIT	
SAN DIEGO, CA 92101-2926			PAPER NUMBER	

1635

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

817

Office Action Summary	Application No. 09/856,655	Applicant(s) SWEET ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 4 and 5, drawn to a method of detecting immunostimulatory DNA comprising detection of complexes, classified in class 435, subclass 6.
- II. Claims 2-5, drawn to a method of detecting an agonist of immunostimulatory DNA comprising detection of complexes, classified in class 435, subclass 6.
- III. Claims 2-5, drawn to a method of detecting an antagonist of immunostimulatory DNA comprising detection of complexes, classified in class 435, subclass 6.
- IV. Claims 6, 7, drawn to a kit for detecting immunostimulatory DNA, classified in class 435, subclass 6.
- V. Claims 8, 11 and 12, drawn to a method of detecting an immunostimulatory DNA comprising measuring macrophage cellular response, classified in class 435, subclass 3.
- VI. Claims 9, 11 and 12, drawn to a method identifying an immunostimulatory DNA antagonist comprising measuring macrophage cellular response, classified in class 435, subclass 3.

- VII. Claims 10, 11 and 12, drawn to a method of identifying an immunostimulatory DNA agonist comprising measuring macrophage cellular response, classified in class 435, subclass 3.
- VIII. Claims 13 and 18, drawn to immunostimulatory DNA, classified in class 536, subclass 23.1.
- IX. Claims 14 and 19, drawn to immunostimulatory antagonists, classified in class 514, subclass 1.
- X. Claims 15-17 and 20, drawn to immunostimulatory agonists, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, V, VI, VII and IV, VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The compositions, compounds and kits of Groups IV, VIII-X are not used in the methods of Groups I, II, III, V, VI, VII. The function and effects of the products of Groups IV, VIII-X are completely different and distinct from the operation, function and effects of the methods of Groups I, II, III, V, VI, VII, which detect the presence of

immunostimulatory DNA, antagonists or agonists thereof. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions I and II and III and V and VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I, II, III, V, VI and VII comprise steps which are not required for or present in the methods of the other groups: Detecting the presence of immunostimulatory DNA, antagonists or agonists thereof, comprising detecting a complex or comprising detecting a macrophage cellular response. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions IV and VIII and IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are chemically, biologically, structurally and functionally distinct from each other and thus one does not render the other obvious. The immunostimulatory DNA of Group VIII, the antagonists of Group IX, the agonists of Group X and the kit of Group IV are not required to produce

each other. Therefore, the inventions of the different groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER